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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/564,229 | 10/02/2006 | Eva Blychert | 1103326-0902 | 7595 |

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PATENT DEPARTMENT
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| EXAMINER | |
|---|---|
| WESTERBERG, NISSA M | |
| ART UNIT | PAPER NUMBER |
| 1618 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/06/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,229 | BLYCHERT ET AL. | |
| | Examiner | Art Unit | |
| | Nissa M. Westerberg | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10,12-18 and 21* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-10,12,13,15-18 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. Applicants' arguments, filed April 28, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 3, 5, 8 – 10, 12, 13, 15 – 18 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (Am J Health Sys Pharm, 2002) in view of Bergstrand et al. (US 5,817,338) and Morris et al. (US 5,869,118). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 2, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Applicants have surprisingly found that the higher the viscosity of the aqueous suspension the thinner the gastric tubes can be used within certain limits. This argument is unpersuasive. Applicants prepare one formulation and administer that formulation in the instant specification. The viscosity of this composition is not recited. There is also no data comparing delivery of that formula with the preparations of the cited prior art. Arguments without factual support are mere allegations and are not found persuasive.

Applicants also argue that White fails to appreciated that the efficient transit of the enteric coating layered pelts through thin (e.g., CH5 to CH 10) gastric tubes is possible with a high viscosity/dispersion comprising a thickener due to the statement that efficient transit of esomeprazole as compared to other may be due to the smaller size and weight of the esomeprazole particles. Bergstrand is silent as to the use of

thickeners and recites the known disadvantages. The products of Morris discloses that "high viscosity products (those over 0.05 Pa s or 50 cps) under high level of shear stress, are not useful for tube feeding or through a nipple" (col 2, ln 21 - 29). These arguments are unpersuasive. The range of the citer prior is over 0.05 Pa s and those values are measured using a Brookfield Viscometer using a #1 spindle at room temperature and at 60 rpm (col 2, ln 28 – 29). The range of the amended claims includes 0.05 Pa s as the lower end point. Therefore, there appears to be overlap and/or the ranges are so close that one skilled in the art would expect them to have the same properties (see MPEP 2144.05). Also, the value in the instant claims are determined from the flow-curve of a rheometer equipped with a plate-plate geometry at a shear rate of 10 $s^{-1}$ with no requirements on the temperature at which the measurement is made. Additionally, one skilled in the art would optimize the viscosity of the preparation with the amount and types of thickeners used to prevent sedimentation of the pellets of enteric coated proton pump inhibitors. The acceptable viscosity will depend on the diameter of the gastric tube used, temperature and the method by which the composition is added to the tube. Compositions can flow through the tube by gravity, by pressure exerted by a syringe (the method described by White et al., see, fore example, p 2086, col 2) or by an enteral pump (col 10, ln 43 – 44 of Morris et al.). Generally, compositions will be less viscous at higher temperatures (e.g. body temperature) than at lower temperatures (e.g., room temperature). Taken as a whole, it would be obvious to one of ordinary skill in the art to optimize the viscosity of the suspension of enteric coated, proton pump inhibitor pellets. Applicants have not

presented any persuasive evidence as to the criticality of the claimed viscosity range and/or evidence of the unexpected properties of the claimed method that is sufficient to overcome the prime facie case of obviousness.

6. Claims 1 – 5, 8 – 10, 12, 13, 15 – 18 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over White et al., Bergstrand et al. and Morris et al. further in view of Calanchi et al. (US 6,261,602). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed November 2, 2009 and those set forth below.

In addition to the arguments set forth above in regards to White et al., Bergstrand et al. and Morris et al. above, Applicant also argues that Calanchi teaches away from the present invention. The sachet dosage form with a granular base product of thickening agent and disintegrating agents is used as a carrier of pharmaceutical compositions that are capable of rapid suspension in water or aqueous media including saliva, but can also be added to a glass of water. For the claimed pediatric population, administration of tablets, capsules or pellets mixed with soft foods or juices is not an option. The administration routes of Calanchi et al. are inapposite to the administration route of the claimed method. These arguments are unpersuasive. Calanchi et al. was not cited for its teachings of a dissolving in the mouth or in a glass of water and subsequent oral administration of the composition. Calanchi et al. was cited for teaching the inclusion of ingredients including xanthan gum, flavoring agents and sweeteners in pharmaceutical suspensions (a full discussion can be found on p 8 of the November 2,

2009 Office Action). The particular thickeners used and the excipients/additives which can be added to a suspension are not exclusive to a particular administration mode. The gastric tube administration and difficulties in administering such oral forms are disclosed by the primary reference of White et al. Despite the different administration modes of the prepared pharmaceutical preparations, Calanchi et al. does not teach away from the use of xanthan gum, sweetener or flavoring agents in pharmaceutical suspensions and this rejection is maintained.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW